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April 21, 2008

### **BY E-FILE**

The Honorable Mary Pat Thyng  
United States District Court of Delaware  
844 North King Street  
Wilmington, DE 19801

Re: *Human Genome Sciences, Inc. v. Amgen, Inc. et al.*  
C. A. No.: 07-526-SLR-MPT  
Request for Clarification Regarding Issue of Priority for § 146 Appeal

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Dear Judge Thyng:

Defendants Amgen and Immunex ("Immunex") respectfully request clarification of the Memorandum Order regarding the scope of discovery, D.I. 33, ("Order") in the present appeal under 35 U.S.C. §146 ("146 appeal").<sup>1</sup> Specifically, Immunex requests clarification of the order that "the court finds that the issue [of priority] was raised adequately below and that it is subject to this court's review" and consequently "the court will consider the priority issue and the parties may conduct discovery on that issue." D.I. 33 at 19:18-20 and 21:3-4. Because it is unclear whether the Court recognized the effect of the early termination of Interference No. 105,381 ("the '381 Interference") on whether the issue of priority was adequately raised below, Immunex provides and requests consideration of the following information.

While it is the case that Plaintiff Human Genome Sciences ("HGS") filed a priority motion in the '381 Interference, HGS' priority case was never developed, responded to by Immunex or considered by the Board. Moreover, Immunex never had the opportunity to present its own priority case, much less have the issue decided, because the priority phase was terminated before Immunex's time period to file a priority motion. Thus, even if the parties litigate "the priority issue" as directed by the Order, the Court can consider, at best, half of the priority dispute as Immunex's priority case was never raised or decided below. For this reason, the Court should decline to consider HGS' priority case, and remand the priority determination to the Board if a priority determination is necessary after the Court rules on the issues raised in the

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<sup>1</sup> During the hearing of March 7, 2008 regarding this issue, Judge Robinson discussed the issues on appeal : I understand that she [Magistrate Judge Thyng] actually is working on this dispute, and the question is whether it makes sense, given the fact that she has had your letters and discussions, that she continue working on the dispute and that I formally refer this dispute to her, and that when she comes out with her decision, which I think she promised me that it would be shortly, that after that, I meet perhaps with you about differences of opinion, if any, you have regarding what she thinks about her opinion and we can go forward.

D.I. 32, 57:11-20.

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substantive motion phase.<sup>2</sup> Otherwise, the Court may have to consider the priority dispute in parts as the Court considers HGS' priority case in this 146 appeal, then remands to the Board to consider the Immunex priority case, and finally considers the Immunex priority case in a subsequent 146 appeal. Such a piecemeal resolution of the priority dispute would be extended, expensive, and inefficient.

The "priority issue" referenced in the Order involves a plethora of issues, which may include issues of conception, reduction to practice, and diligence, that are framed in each party's priority statement. At the beginning of the '381 Interference, both parties filed priority statements. However, the mere filing of a priority statement does not raise the priority issues (conception, diligence, reduction to practice) for a 146 appeal. "A significant body of case law leads to the conclusion that including a factual assertion within a preliminary statement before the Board is not 'raising an issue' within the meaning of §146." Abbott Labs v. City of Hope, 224 F. Supp. 2d 1200, 1202 (N.D. Ill. 2002) (citing General Instrument Corp. v. Scientific-Atlanta, Inc., 995 F.2d 209, 214 (Fed. Cir. 1993); Conservolite, Inc. v. Widmayer, 21 F.3d 1098, 1102 (Fed. Cir. 1994)).

The issues involved in a priority determination are developed during the priority phase of the interference. Similar to the motion phase, the priority phase is a detailed and multi-staged phase divided into nine sections or "time periods" ("TP"), which occurs over the span of about eight months. Once the priority phase begins, the Junior party files its priority motion (TP 11) and six weeks later, the Senior party files its priority motion (TP 12). Each party may file an opposition to priority motion of the other party (TP 13) and a reply in support of its own priority motion (TP 14). Then, each party may file a request for oral argument, list of issues to be considered, observations, and a motion to exclude evidence presented by the other party in support of their priority brief (TP 15). Oppositions and responses to observations (TP 16) and replies to motions to exclude (TP 17) are then filed. All exhibits used during the priority phase are filed and served, and sets of priority motions are filed with the Board (TP 18). Finally, each party may present oral argument to the Board (TP 19). See Order-Priority Times, Exh. B to D.I. 22. The '381 Interference terminated at the very beginning of the priority phase, just after TP 11, which was only three weeks into the eight-month priority phase. The motions, oppositions, replies, and arguments of TP 12-19 were never presented let alone considered by the Board.

In the '381 Interference, the Board issued the Decision on Motions on March 26, 2007 and a first scheduling order for the priority phase on March 29, 2007, setting TP 11, the time for HGS to file its priority motion, for June 6, 2007. On April 9, 2007, the Board postponed the TP 11 by one month, resetting the due date for HGS' priority motion to July 6, 2007. Order-Priority Times, Exh. B to D.I. 22, 2:16-18 and page 4. That same day, HGS requested reconsideration of the Board's decision that HGS' claims were unpatentable under 35 U.S.C. § 102(e) and that the decision be deferred to the priority phase. The Board denied the request and issued an order to show cause: "As HGS is the junior party and has no patentable claims, **there does not appear to**

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<sup>2</sup> To the extent that objections within 10 days of an Order are required under Fed. R. Civ. P. 72(a) to preserve this issue, Immunex intends and requests that this pleading be considered objections to the portion of the Order considering "the issue of priority" on appeal in this matter.

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**be a reason to continue this interference into the priority phase."** Order to Show Cause, dated June 1, 2007, Exh. A hereto (emphasis added).

HGS filed its priority motion on June 26, 2007, a week and a half early, and improperly filed its priority evidence with its priority motion in TP 11 instead of TP 18 as required by the Board's scheduling order. Order-Expunging Paper, Exh. E to D.I. 22, 2:1-3. On July 27, 2007, the Board terminated the '381 Interference because HGS did not have any remaining patentable claims and specifically stated: "We decline to evaluate HGS' priority case to determine if we should consider HGS' priority case." Order to Show Cause, Exh. D to D.I. 22, 12:2-3. The Board then expunged HGS' priority evidence from the record. Order-Expunging Paper, Exh. E to D.I. 22, 3:6-9.

Immunex never had the opportunity to respond to HGS' priority motion because the '381 Interference terminated on July 27, 2007, long before September 25, 2007 (TP 13), the due date for the oppositions to priority motions. Similarly, Immunex never had an opportunity to raise its priority case because the '381 Interference terminated well before August 17, 2007 (TP 12), the due date for Immunex's priority motion. Order-Priority Times, Exh. B to D.I. 22, page 4.

Because the '381 Interference terminated three weeks after the priority phase began, HGS' priority case was never developed, responded to by Immunex or considered by the Board. Immunex's priority case was never briefed, developed, responded to by HGS or considered by the Board. "The public interest in ensuring that only those patents that claim patentable subject matter are issued and maintained is best served when a district court considering review of a decision of the Board resolves all issues of priority and patentability that have been raised **and fully developed.**" Rexam Indus. Corp. v. Eastman Kodak Co., 182 F.3d 1366, 1370 (Fed. Cir. 1999) (emphasis added). The "priority issue" before this Court, no matter how it is defined, was not fully developed and should not be considered in this 146 appeal. Goliath Hundertzente Vermoögensverwaltungsgesellschaft mbH v. Yeda Research & Development Co., 2003 WL 22830014 (D.D.C. 2003) ("By first allowing the Board to make factual and legal findings, the court can take advantage of the Board's specialized knowledge of the complex patent issues in dispute.").

It is unclear from the Order whether the Court recognized that, because the '381 Interference terminated so quickly after the priority phase began, Immunex's priority case was never raised. The Court noted that "it is more efficient for both the parties and the court to address the scope of review and appropriate discovery (to the extent possible) at this stage of the litigation." D.I. 33, 19:15-17. Consequently, Immunex brings this issue to the Court's attention to clarify its order that "the court finds that the issue [of priority] was raised adequately below and that it is subject to this court's review" and that "the court will consider the priority issue and the parties may conduct discovery on that issue." Immunex would welcome the opportunity to discuss this matter further with the Court if the Court so wishes.

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United States District Court of Delaware  
April 21, 2008

Respectfully,

*/s/ Melanie K. Sharp*

Melanie K. Sharp (No. 2501)

cc: Clerk of the Court (Hand Delivery)  
John G. Day, Esquire (via e-mail)  
Steven J. Balick, Esquire (via e-mail)  
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# **EXHIBIT A**

The opinion in support of the decision being entered today is not binding  
precedent of the Board

Paper 114

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES  
(Administrative Patent Judge Richard E. Schafer)

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**Human Genome Sciences, Inc.,**  
Junior Party  
(Application 10/005,842-IFW  
Inventors: Jian Ni, Reiner L. Gentz,  
Guo-Liang Yu and Craig A. Rosen),  
v.  
**Immunex Corp.,**  
Senior Party  
(Patent 6,642,358  
Inventors: Charles Rauch and Henning Walczak).

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Patent Interference No. 105,381 (RES)

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**Order to Show Cause - Bd.R. 202(d)**

1 In a decision on motions entered on March 26 2007, all of Human  
2 Genome Sciences (HGS) involved claims were held to be unpatentable  
3 under 35 U.S.C. § 102(e). Paper 101, p. 29-38. That decision was  
4 maintained on reconsideration. Paper 113. As HGS is the junior party and

1 has no patentable claims, there does not appear to be a reason to continue  
2 this interference into the priority phase.

3 On or before **June 15, 2007**, HGS is ordered to show cause why  
4 judgment should not be entered against it.

/Richard E. Schafer/  
RICHARD E. SCHAFER  
Administrative Patent Judge

cc:

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